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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,297	12/19/2000	Genevieve Hansen	S-30025D	5673

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SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/20/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,297

Applicant(s)

HANSEN, GENEVIEVE

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, and Amendment B, Papers No. 7 and 8 filed April 29, 2002. Applicant elects Group I, claims 1-8, with traverse, stating that while the inventions of groups I and VII are patentably distinct, these inventions are related and are not properly subject to a restriction requirement. Applicant's traversal is unpersuasive for the following reasons: the inventions have different starting materials, different method steps and different end products. Thus, while the inventions may be related, the search of the prior art of one invention is not co-extensive with that of another. Accordingly, the restriction requirement is maintained.

Claims 1-19 are pending. Claims 9-19 are nonelected. Claims 1-8 are examined in the instant application. This restriction is made FINAL.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate. The address for ATCC (page 7) needs to be updated.

Sequence Listing

3. Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

4. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, is attached to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, a "gene of interest" is unclear because

- "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired.
- "exposing" is unclear. The term "exposing" should be amended to "contacting", as "exposing" could be in the same vicinity without being in contact.

Art Unit: 1638

- “under conditions which inhibit AIN” is unclear because it is not clear whether the Agrobacterium are under those conditions, or the plant cell or tissue are under those conditions, or both.
- Claim 1 is an incomplete method claim because the final step of the method does not produce the desired product.

In Claim 2,

- “after heat-shock treatment” is unclear because “treatment” of what is not clear. Is the treatment of Agrobacterium, or of the plant cell or tissue, or both?

In claim 4,

- “chemical inhibitor” is unclear. Is the “inhibitor” a chemical, or does the “inhibitor” inhibit a chemical?
- “phophatase” is misspelled.

In claim 5, how are “ethylene inhibitors”, and “ethylene synthesis inhibitors” different?

In claim 7,

- inhibiting AIN” is unclear; are “protein” or both “mRNA and protein” inhibiting agents?

Claim 8 is an incomplete method claim because the final step of the method does not produce the desired product.

Clarification and/or correction are required.

Claim Rejections - 35 USC112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

while being enabling for a method of transforming a maize or a wheat cell or tissue with a gene of interest, comprising contacting said plant cell or tissue with *Agrobacterium* in the presence of AgNO_3 , or in the presence of a nucleotide sequence encoding p35, iap, or dad-1, and the where *Agrobacterium* comprises a vector comprising a nucleic acid sequence of interest,

does not reasonably provide enablement for:

unspecified conditions which inhibit *Agrobacterium* induced necrosis (AIN), or the broad scope of inhibiting agents or inhibitors.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enablement issues are "conditions which inhibit", "agent", "a nucleotide sequence", "ethylene inhibitors, ethylene synthesis inhibitors, gibberellin antagonists, and phosphatase inhibitors".

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

Art Unit: 1638

The nature of the invention. Applicant's invention is a method of transforming plants with Agrobacterium, whereby the transformation includes conditions which inhibit Agrobacterium induced necrosis (AIN) of the tissue. Only monocots appear to show this AIN, and AIN is thought to be one of the barriers to routine Agrobacterium-mediated transformation of monocots. Applicant proposes solving this problem by use of heat-shock to the tissue or by the use of chemical inhibitors or chemicals. The prior art teaches the use of AgNO₃ as a chemical inhibitor to solve this problem. Applicant teaches heat-shock, AgNO₃, and nucleotide sequences encoding p35, iap, or dad-1 to solve this problem. These three conditions of heat-shock, AgNO₃, and the three nucleotide sequences, are very different and do not teach one of skill in the art how to predictably practice this invention commensurate in scope with these claims.

The breadth of the claims. The claims are drawn broadly to a method of transforming any plant, any conditions which inhibit AIN, any agent or chemical inhibitor of AIN, any ethylene inhibitors, any ethylene synthesis inhibitors, any gibberellin antagonists, any phosphatase inhibitors, any nucleotide sequence, any mRNA or protein inhibiting AIN.

Re "conditions which inhibit" AIN:

Applicant teaches two conditions for inhibition of AIN: heatshock treatment, and the use of silver nitrate as a chemical ethylene inhibitor. Applicant does not give guidance for what is special about these conditions, which allow them to function in the desired manner. It is trivial for one to "inhibit" a given reaction or event, what is difficult is the selective inhibition. Putting tissues and Agrobacterium together in a minus 70

Art Unit: 1638

freezer, or subjecting them to gamma radiation will inhibit AIN. Applicant does not teach how to selectively inhibit AIN, while maintaining all other desired functions required for transformation and function. It is unpredictable that any given condition would function as desired. Finding proper conditions would require a myriad of experiments of a multiplicity of conditions. In fact it would require an infinite number of experiments to find conditions which function in the desired manner. This would require excessive experimentation, and impose undue burden on one of ordinary skill in the art.

Re an agent, and ethylene synthase inhibitors, gibberellin antagonists, and phosphatase inhibitors

Applicant claims "an agent" inhibiting AIN. Many agents, physical or chemical, exist which could inhibit AIN. These agents could function singly, together, sequentially or concurrently. In terms of a chemical inhibitor, Applicant teaches AgNO₃. The breadth encompasses all known chemicals and yet to be discovered compounds. Applicants teach no examples of ethylene synthase inhibitors, gibberellin antagonists or phosphatase inhibitors. For the highly specialized function of inhibiting AIN, it is unpredictable than any given compound would function in the desired manner. So one of ordinary skill would have to screen many chemicals at many different concentrations and conditions, to practice the claimed invention, imposing undue burden and excessive experimentation.

Re "a nucleotide sequence" as the agent which inhibits AIN: Applicant claims any nucleotide sequence. Applicant teaches the coding sequences of *p35*, *iap* and *dad-1*. The nucleotide sequence can be DNA or RNA of any length or any sequence. No

Art Unit: 1638

guidance is given other than the sequences above. For the highly specialized function of inhibiting AIN, it is unpredictable that any given sequence would function in the desired manner. It would require many experiments of different types of nucleic acids, of many different lengths, of many different sequences. In fact it would require that an infinite number of experiments, to find nucleic acids which function in the desired manner. This would require excessive experimentation, and impose undue burden on one of ordinary skill in the art.

In view of the breadth of the claims (a method of transforming any plant, any conditions which inhibit AIN, any agent or chemical inhibitor of AIN, any ethylene inhibitors, any ethylene synthesis inhibitors, any gibberellin antagonists, any phosphatase inhibitors, any nucleotide sequence, any mRNA or protein inhibiting AIN), the nature of the invention, the unpredictability of the art, the lack the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

The conditions of Agrobacterium induced necrosis are only exhibited in monocot plants; there is no evidence for this phenomenon with dicot plants.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman et al, US 4,956,282, issued September 11, 1990.

Goodman teaches a method of transforming a plant cell or tissue with a gene of interest, comprising exposing said plant cell or tissue to Agrobacterium, wherein said Agrobacterium comprises a vector comprising said gene of interest (col 8 lines 40-50). Goodman further teaches chemicals and nucleotide sequences. Since the conditions are unspecified, and the chemicals and nucleotide sequences are unspecified, and there is no evidence of Agrobacterium induced necrosis, the conditions utilized by Goodman, must inherently inhibit AIN.

Accordingly, Goodman anticipates the claimed invention.

9. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated De Block, M, et al, Plant Physiol, 1989, vol 91, 694-701.

De Block teaches a method of transforming plant tissue, and a method of making a fertile, transgenic plant (Figure 1, p 698, final paragraph p 698), by exposing the tissue to Agrobacterium transforming a plant cell or tissue with a gene of interest comprising exposing said plant cell wherein said Agrobacterium comprises a vector comprising said gene of interest (Abstract, p 694). De Block also teaches the ethylene inhibitor AgNO₃ (Abstract; p 695, 1st paragraph and Table II). Since there is no evidence of Agrobacterium induced necrosis, the conditions utilized by De Block, must inherently inhibit the AIN.

Art Unit: 1638

Accordingly De Block anticipates the claimed invention.

Claim Rejections - 35 USC § 103

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR

11. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of US# 6,162,965. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant case are broader and therefore, encompass the '965 claims. Thus, the species claims of '965 render obvious, the genus claims, of instant application. Furthermore, no restriction of the parent case, 09/089,111 was required by the Office.

The claims of the instant application are drawn to a method of transforming

Art Unit: 1638

plant or tissue with a gene of interest, comprising exposing said plant cell or tissue to Agrobacterium under conditions which inhibit Agrobacterium induced necrosis (AIN), wherein said Agrobacterium comprises a vector comprising said gene of interest.

The claims of '965 are drawn to a method for transforming a plant cell or tissue with a gene construct, comprising heat shocking said plant cell or tissue before co-cultivating with Agrobacterium, wherein said heat shock treatment inhibits Agrobacterium induced necrosis in said plant cell or tissue, and said Agrobacterium comprises a vector comprising said gene construct. The '965 claims are further drawn to use of nucleotide sequences coding for p35, iap or dad-1 as agents for inhibiting AIN.

Accordingly, the claims of the instant application encompass the claims of the '965 patent.

Remarks

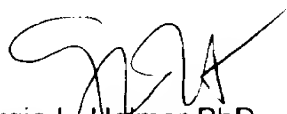
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

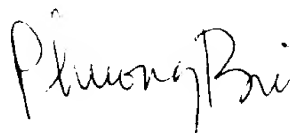
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Art Unit: 1638

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Georgia L. Helmer PhD
Patent Examiner, art unit 1638
June 13, 2002



PHUONG T. BUI
PRIMARY EXAMINER